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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/389,428	09/03/1999	HANS-JUERGEN KUHR	BMID9813US	5380

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EXAMINER

NGO, LIEN M

ART UNIT	PAPER NUMBER
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3727

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/389,428

Applicant(s)

KUHR ET AL.

Examiner

LIEN TM NGO

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-32 and 43-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 is/are allowed.
- 6) ☒ Claim(s) 22-25, 27-32 and 43-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 22-25, 27-30, 43, and 46-50 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (4,821,878). In regard to claims 22-23, 25 and 48, Jones discloses, in figs. 5, 11, 14 and 15-18, a system comprising a tool 4 which is capable of using as a lancing device to hold a needle (1, 62) which is capable of using as a lancet to pierce the skin of a person for collecting a body fluid, a needle magazine (40, 54), a transport device (a hand in fig. 14 or a spring in fig. 15), and an opening 56 in which the tool can be inserted to remove an individual needle from the magazine. In regard to claims 24, 27-30, the magazine has a flat angular shape (fig. 15) or a round disk shape (fig. 14) and the transport device is driven by a spring mechanism 63. In regard to claims 46 and 47, the tool comprising a holding tongue (16, 17 or 60, 61) having a barb (21, 22) and an ejector (23, 24). In regard to claim 52, means 60 for ensuring proper positioning of the needle prior to removal of the needle from the magazine.
3. Claims 22, 23, 27-29, 31, 43, 50 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Nguyen et al. (5,829,589). In regard to claims 22-23, 25 and 43, Nguyen et al.

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disclose, in figs 3-5, a system comprising a lancing device 1 (delivery pen), a lancet magazine 35, a transport device 30 (the device 30 is capable rotate around the cover 20 when the cover 20 is held in place), and an opening 21 into which the lacing device can be inserted to remove an individual lancet from the lancet magazine. The system further comprising a plurality of lancets (needles) 100. In regard to claims 24, 27-29, the lancet magazine has a round disk shape, and the transport device is a manually operated slide. In regard to claims 31, a pin 46 located in the opening of the magazine and a groove 55 in the tip of the lancing device. In regard to claims 50 and 51, the lancet comprising a lancet body 102 having opposed recesses (recesses between splines 110) and pins 101. Note that, Nguyen et al. delivery pen is capable of using as a lancing device to hold a needle body 100 which is capable of using as a lancet to pierce the skin of a person for collecting a body fluid.

The statement of intended use has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Nguyen device, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen (5,829,589). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the groove 55 in the tip of the lancet device with a pin, and replace the pin 46 in the magazine opening with a groove, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

6. Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen (5,829,589) in view of Nguyen (5,873,462). Nguyen 598 does not disclose the needles (lancets) having a protective sheaths. Nguyen 462 teaches, in fig. 6, needles (lancets), stored in a magazine, having protective sheaths which is capable to be removed when a lancing device is inserted into the magazine. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the Nguyen 598 needles with protective sheaths, as taught by Nguyen 462, in order to protect the needle from contamination.

Allowable Subject Matter

7. Claims 26 is allowed.

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Response to Arguments

8. Applicant's arguments filed 8/20/02 have been fully considered but they are not persuasive.

9. Applicant's arguments with respect to claims 22-25, 27-30, 43, and 46-50 and 52 have been considered but are moot in view of the new ground(s) of rejection.

10. In response to applicant's argument that Nguyen '589 does not teach claimed structural limitations and says nothing about using its pen needles to collect body fluid. However, that is not found convincing because Nguyen '589 disclose all the limitations substantially as claimed as pointed out in the rejection above and the statement of intended use has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Nguyen device, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In response to applicant's argument that Nguyen '589 does not teach a transport device adapted to transport lancets. However, that is not found convincing because although the container 30, which examiner considers as the transport device, does not move, but the cover 20 is rotatably mounted on the container 30; therefore, when the cover is held in place, the container 10 is capable to move or rotate around the cover to transport the needle to the opening of the cover.

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11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Moulton et al., Simons et al., Mastri et al. and Stone et al. teach transport magazines and delivery tools.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lien Ngo whose telephone number is (703) 305-0294. The examiner can normally be reached Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful. The examiner's supervisor, Lee Young, can be reached at (703)308-2572. The Group FAX number is (703) 305-3597.

Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist at (703) 308-1148.

Lien Ngo

November 22, 2002



LEE YOUNG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700